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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,918	09/29/2006	Yoshinori Abe	4633-0189PUS1	5532

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EXAMINER	
GUGLIOTTA, NICOLE T	
ART UNIT	PAPER NUMBER
1794	

NOTIFICATION DATE	DELIVERY MODE
03/23/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/594,918	ABE ET AL.	
	Examiner	Art Unit	
	NICOLE T. GUGLIOTTA	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2, 4, 5, 8 - 10, 12 - 15, 24 - 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 4, 5, 8 - 10, 12 - 15, 24 - 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 9, 2009 has been entered.

Examiner's Note

2. Examiner acknowledges the amendments made to claims 2, 4, 5, 24, and 26, as well as the cancellation of claims 1, 3, 6 -7, 11, and 16 – 23, and the addition of claim 28.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 5 & 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. Claim 27, which requires the biocompatible component to be a peptide, protein, nucleobase or an amino acid, is dependent upon claim 26, which requires a biocompatible component to be *ionically* bonded to the DLC film. Examiner was unable to find support in Applicant's disclosure for a peptide, protein, nucleobase or an amino acid *ionically* bonded to the diamond-like carbon film. Therefore claim 27 is rejected for lack of written description.

5. Claim 5 amendment states "wherein the biocompatible component is a polymer containing silicon."

a. Examiner can find no support in Applicant's original specification to support "a polymer containing silicon" as the biocompatible component. More specifically, claim 1, which claim 5 is dependent upon, presently limits the polymer to be "a polymer of vinyl monomers, vinylidene monomers or cyclic vinylene monomers." Examiner can find no support in Applicant's specification for any of these specific types of polymers containing silicon. Examiner particularly notes the following areas of Applicant's specification:

i. Paragraph [0015] of Applicant's specification states: "the biocompatible component may be a polymer formed from vinylmonomers which contain fluorine and are grafted to the surfaces of the diamond-like carbon film, or may be a molecule containing silicon." Based on this excerpt, it would be clear to one

of ordinary skill in the art to understand the silicon referenced does not correspond with the polymer referenced.

ii. Paragraph [0060] of Applicant's specification states: "A functionality component containing in the molecule a functional group which cause a reaction with the functional group introduced to the surface of the DLC film, for example…a trialkyloxysilane group such as trimethoxysilane, triethoxysilane, etc. can be readily be covalent-bonded to the surface of the DLC film." Examiner concedes a molecule containing silicon (a trialkyloxysilane) is the biocompatible component based upon this excerpt from Applicant's disclosure. However, trialkyloxysilanes are not polymers. Therefore, there is no support for the amendment "wherein the biocompatible component is a polymer containing silicon."

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 2, 4, 8, and 12 – 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woo et al. (U.S. Patent No. 6,761,736 B1).

8. In regard to claims 2 and 4, Woo et al. disclose “biocompatible material in addition to the diamond-like carbon coated polymer substrate…within the same component as the diamond-like carbon coated polymer material or in separate components" (Col. 6, Line 67 - Col. 7, Line 6). The DLC is formed on a polymer substrate (corresponds to applicant’s “base material”) (Col. 2, Lines 48 – 51). Such biocompatible components include vinyl polymers (e.g. polytetrafluoroethylene). Woo et al. are silent in regard to whether the biocomponent is directly applied on top of the DLC, much less any methods used to apply it.

9. In regard to the biocompatible component "grafted to a surface", Examiner considers this a product-by-process claim. Examiner refers applicant to MPEP § 2113 [R - 1] regarding product-by-process claims. “The patentability of a product does not depend on its method or production. If the product in the product-by-process claim is the same as or obvious from a product or the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777, F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citation omitted).

Once the examiner provides a rationale tending to show that the claimed product appears to be same or similar to that of the prior art, although produced by a different process, the burden shifts to the applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218, USPQ 289, 292 (Fed. Cir. 1983)

10. In regard to claim 8, Woo et al. disclose polysulfones are also an appropriate biocompatible material (Col. 8, Line 1).

11. In regard to claim 12, Woo et al. disclose the diamond-like carbon coating can be applied to a sawing cuff formed from a polymer fabric (corresponds to Applicant's "macromolecular material") (Col. 6, Lines 31 – 32).

12. In regard to claim 13 - 15, Woo et al. disclose the polymer substrate containing a DLC film and a biocompatible material are used for medical article that contact a patient's bodily fluids (Col. 2, Lines 48 – 51). Medical articles include catheters and prostheses (Col. 1, Lines 5 – 21).

13. Claims 2, 4, 5, 12 - 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steffen et al. (*Surf. Interface Anal.* **29**, 386 – 391 (2000); submitted by applicant), in view of Palmaz et al. (U.S. Patent No. 6,537,310 B1).

14. In regard to claims 2 and 4, Steffen et al. disclose a diamond-like carbon (DLC) film system that consists of a chemically inert, uniform, dense and highly tetrahedrally bonded, hydrogenated amorphous carbon film (ta-C:H) with high adherence to the substrate and bioactive heparin macromolecules that are covalently bonded to the ta-C:H film surface (Figure 1 & Page 387, 2nd Col., 2nd

paragraph). However, Steffen et al. do not disclose the biocompatible layer to contain silicon of vinylmonomers containing fluorine.

15. Palmaz et al. disclose

> numerous attempts to increase endothelialization of implanted stents, including imparting a diamond-like carbon coating onto the stent (U.S. Pat. No. 5,725,573), coating the stent, under ultrasonic conditions, with a synthetic or biological, active or inactive agent, such as heparin, endothelium derived growth factor, vascular growth factors, silicone, polyurethane, or polytetrafluoroethylene (U.S. Pat. No. 5,891,507), coating a stent with a silane compound with vinyl functionality, then forming a graft polymer by polymerization with the vinyl groups of the silane compound (U.S. Patent No. 5,782,908), *grafting monomers, oligomers or polymers onto the surface of the stent using infrared radiation*, microwave radiation or high voltage polymerization to impart the property of the monomer, oligomer or polymer to the stent (U.S. Pat. No. 5,932,299) (Col. 6, Lines 29 - 54).

16. It would have been obvious to one of ordinary skill in the art at the time of the invention to graft biocompatible layers containing vinylfluoride monomer molecules (polytetrafluoroethylene), in place of the heparin disclosed by Steffen et al., because such components and methods have been previously taught for increasing endothelialization and antithrombogenicity, as disclosed by Palmaz et al.

17. In regard to claim 5, Palmaz et al. disclose previous art (U.S. Patent No. 5,782,908) teach "coating a stent with a silane compound with vinyl functionality, then forming a graft polymer by polymerization with the vinyl groups of the silane compound" (shown above). This disclosure teaches it was well known at the time of applicant's invention that silane compounds with vinyl functionality were used to increase antithrombogenicity and therefore it would have been obvious to

one of ordinary skill in the art at the time of the invention to use as a biocompatible component in the invention of Steffen.

18. In regard to claim 12, Steffen et al. disclose the substrate materials (base materials) may include Si(100) wafers (Page 388, Col. 1, first paragraph of the experimental section).

19. In regard to claims 13, 14, and 15, Steffen et al. disclose the film composed of DLC and surface-immobilized bioactive molecules optimize hemocompatibility for artificial implants of the cardiovascular system (Abstract and Page 386, Col.1, paragraph 1). In addition, the use of DLC films on polymers give rise to a universal application of these carbon materials for medical devices, such as total joint replacements, heart valves, catheters, stents, intravascular insertion devices and more (Page 388, Col. 1, first paragraph).

20. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steffen et al. and Palmaz et al., as applied to claim 2 above, and further in view of Lemelson et al. (U.S. Patent No. 6,083,570).

21. Steffen et al. disclose a biocompatible layer attached to a diamond-like carbon (DLC) layer, which is applied to a substrate (base material). However, Steffen et al. do not disclose the use of an intermediate film between the DLC and the substrate (base material).

22. Lemelson et al. disclose articles with synthetic diamond or diamond-like carbon coatings with an intermediate amorphous metal bonding later. The residual stress in diamond and diamond-like thin film coatings applied to metal, cermet and ceramic substrates can be reduced to acceptably low levels by using an intermediate film coating of amorphous ("glassy") metal (Column 3, Lines 54 - 65). Such articles include dental tools and medical prostheses or implants intended for long-term use inside the human body (Column 4, Lines 4 – 11). The intermediate layer may be comprised of carbides or silicon. SiC is most preferred (Column 4, Lines 33 - 38).

23. It would have been obvious to one of ordinary skill in the art at the time of the invention that the addition of an intermediate SiC layer between the DLC and substrate in the disclosure of Steffen et al. would help to reduce the residual stress in diamond-like carbon thin film coatings used for medical applications. An organosilicon intermediate layer for increased adherence between a substrate and a DLC is also disclosed by Kato et al. (U.S. 5,763,072).

24. Claims 24 - 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baselt (U.S. Patent No. 5,981,297).

25. Baselt disclose a biosensor for binding assays used for diagnostic testing (Col. 1, Lines 13 - 16), which comprises an antibodies (gamma globulin proteins) covalently attached to the insulating coating over magnetoresistive elements (Col. 6, Lines 60 – 63). This insulating coating may be a thin coating of

siliconoxynitride, polymer, diamond-like carbon, or other insulating material (Col. 6, Lines 47 – 50).

26. It would have been obvious to one of ordinary skill in the art for proteins, such as antibodies, to be covalently attached to a diamond-like carbon layer, as Baselt has disclosed a diamond-like carbon layer as a possible insulating coating for the magnetoresistive elements of his biosensor.

27. Claims 8, 26 – 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steffen et al. and Palmaz et al., as applied to claim 2 above, and further in view of Suto et al. (J. Bio. Chem. No. 280, No. 3, pp. 2126 - 2131).

28. Steffen et al. teach heparin ionically bonded to a DLC layer (heparin being negatively charged). Palmaz et al. disclose, as discussed for claim 2, coating the stent with heparin or other biomolecules, such as endothelium derived growth factors or vascular growth factors (proteins), in order to increase endothelialization of implanted stints. However, Palmaz et al. is silent in regard to how the vascular growth factors are bonded to the surface of the stint.

29. Suto et al. disclose vascular endothelial growth factor-A (VEGF-A) is mostly negatively charged (pg 2130, 1st column), due to negatively charged amino acid residues containing carboxyl groups, such as aspartate (D63) and glutamate (E64) (Figure 2).

30. As discussed for claim 2 above, it would have been obvious to one of ordinary skill in the art at the time of the invention that a biocompatible

component, such as PTFE or vascular growth factors may be substituted for the heparin of Steffen et al. (disclosed by Palmaz et al.), because the biocompatible components have been shown to increase endothelialization of implanted stents. Suto et al. teach vascular endothelial growth factor-A is negatively charged due to negatively charged amino acids at it's surface. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that a negatively charged vascular growth protein disclosed by Palmaz et al. would bind to the DLC layer in the same manner (an ionic bond) as the negatively charged heparin disclosed by Steffen et al.

31. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Steffen et al. and Palmaz et al., as applied to claim 2 above, and further in view of Han et al. (U.S. Patent No. 6,268, 161 B1).

32. In regard to claim 28, Steffen et al. and Palmaz et al. disclose biocompatible components, such as vinyl polymers, for coating medical devices. However, they are silent in regard to the specific use of 2-hydroxypropyl methacryl amide (HPMA).

33. Han et al. disclose HPMA is a tough, flexible polymer that is highly biocompatible; as well as inert and nondegradable *in vivo*, a preferred trait for biosensors that are to be implanted into the human body (Col. 8, Lines 8 – 16).

34. It would have been obvious to one of ordinary skill in the art at the time of the invention to use HPMA in the invention of Palmaz et al. as a preferred vinyl polymer because HPMA is inert and nondegradable *in vivo*.

Response to Arguments

35. Issues under 35 U.S.C. § 112

36. Applicants argue, "Applicants respectfully refer the Examiner to claim 2 as shown herein, wherein the disputed claim language is no longer recited…Reconsideration and withdrawal of this rejection are respectfully requested" (Remarks, Pg 7).

37. Examiner withdraws the rejection.

38. Applicants argue, "Claims 24 - 27 stand rejected under 35 U.S.C. § 112, second paragraph, for asserted lack of definiteness (see Office Action 4 – 5, page 3). Applicants respectfully traverse and refer the Examiner to the disputed claims as shown herein as this rejection has been overcome… Accordingly, reconsideration and withdrawal of this rejection are respectfully requested" (Remarks, Pgs 7 – 8).

39. Examiner withdraws the rejection.

40. Issues under 35 U.S.C. § 102(b)

41. Applicants argue, “Tanga ‘908 and Steffen et al. fail to disclose or suggest this grafted structure and/or the polymer. The cited references do not suggest such a structure is even available” (Remarks, Pg 8).

42. "Applicants note paragraph 11 of the Office Action wherein the Examiner states that claims 2 – 4 are product-by-process claims due to the recitation of ‘graft polymerization’. Reconsideration is requested in light of the claim amendments as seen herein the previous assertion by the USPTO was the ‘graft polymerization’ did not result in a different structure. In the present invention, a biocompatible component is grafted to a surface of a diamond-like carbon film, and this structure is not disclosed in the cited references” (Remarks, pg 9).

43. Examiner maintains claim 2 is product-by-process claim because “grafted” is a means of applying the biocomponent to the DLC layer, which does not result in a different product than any other known method, such as CVD.

44. ***Issues under 35 U.S.C. § 103(a)***

45. Applicants argue against the combinations of Steffen et al. and Palmaz '310 and over the combination of Steffen et al. and Lemelson '570 for claims 4, 5, 9, and 10 because these claims are dependent on claim 2 and therefore the arguments for claim 2 above apply to these claims as well.

46. Examiner maintains claim 2 is product-by-process claim because “grafted” is a means of applying the biocomponent to the DLC layer, which does not result in a different product than any other known methods, such as CVD.

47. Applicants argue they have unexpected results of medical material having excellent biocompatibility and as a medical instrument formed of the medical material.

48. Applicant's arguments filed January 9, 2009 have been fully considered but they are not persuasive. Applicant has failed to show how their invention of a biocompatible component attached to a DLC layer has unexpected results of excellent biocompatibility compared to the prior art cited (Woo et al., Steffen et al., Baselt, etc.), whom also teach biocompatible components attached to a DLC layer with excellent biocompatibility.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE T. GUGLIOTTA whose telephone number is (571)270-1552. The examiner can normally be reached on M - Th 8:30 - 6 p.m., & every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on 571-272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David R. Sample/
Supervisory Patent Examiner, Art Unit 1794

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